DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on October 23rd, 2009. Claims 119-126, 148-155, 158-331 are pending in the instant application.

2. The indicated allowability of claims 119-122 and 161 is withdrawn in view of the newly discovered reference(s) to Mastrototaro et al. (USP #6,424,847). Rejections based on the newly cited reference(s) follow.

Information Disclosure Statement

3. IDS submitted on September 3rd, 2009 and December 26th, 2009 have been reviewed in full.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 160, 176, 191, 208, 212, 237, 258, 310, 315 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claims 160, 176, 191, 208, and 310 recite a step of detecting transient non-glucose related signal artifact performed on the calibrated data stream. The specification fails to provide support for such a feature.

7. Claims 212, 237, 292, 315 recite high pass filtering. The specification fails to provide support for such a feature.

8. Claim 258 recites comparing the rate of change with a preselected value. The specification fails to provide support for such a feature.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 119-126, 148-155, 158, 159, 161-175, 177-190, 192-207, 209-211, 213-227, 233-236, 238-248, 254-286, 293-309, 311-314, and 316-326 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parris et al. (US 2002/0026110) in view of Mastrototaro (USP #6,424,847).

11. As to claims 119-122, Parris teaches a method for processing data from a glucose sensor, comprising monitoring a data stream from a glucose sensor (Abs), detecting transient non-glucose related signals and evaluating a severity of the artifact and replacing at least some of the signal values with one or more estimated glucose values ([0239-0243]). Parris fails to teach that the evaluation of the severity is based in part on an amplitude, duration, rate of change, or frequency of the transient non-glucose related signal artifacts. However, Mastrototaro teaches a teaches a glucose monitor calibration method which determines a severity of a signal artifact and replaces one of the signal artifacts with estimated glucose values, wherein the severity is based on

amplitude (col. 8 lines 38-56 - Mastrototaro teaches that the highest and lowest of the sampled values are ignored), duration (col. 10 lines 26-38 – with three or more consecutive samplings exceeding the limit, the threshold is changed), rate of change (col. 9 lines 22-42 - limits are set to depend on acceptable amounts of change from one data point to another), and frequency (col. 11 liens 28-38 - sensitivity ratio can be based on frequency in alternative embodiments). As such, it would have been obvious to one of ordinary skill in the art to modify the method of processing glucose measurement data as taught by Parris with the various methods of determining a severity of a signal artifact as taught by Mastrototaro to obtain results that are more accurately reflective of the user's glucose measurements.

12. As to claim 123, Parris teaches the application of one of a plurality of signal estimation algorithm factors in response to the severity of the signal artifacts (Fig. 13).

13. As to claim 124, Parris teaches the application of a single algorithm with a plurality of parameters that are selectively applied to the algorithm (Fig. 13; several models use a plurality of parameters).

14. As to claim 125, Parris teaches a plurality of distinct algorithms (Fig. 13).

15. As to claim 126, Parris teaches the selective application of a predetermined algorithm that comprises a set of parameters whose values depend on the severity of the signal artifacts ([0248]).

16. As to claim 148, Parris teaches replacing signal artifacts comprises outputting data representative of one or more of the estimated glucose values including a numeric representation ([0243]).

17. As to claim 149, Parris teaches the use of filtered data streams when the signal artifacts meet one or more predetermined criteria. ([0176-0177] - the use of the predictive kinetic method is capable of being used during error causing physiological phenomena such as temperature).

18. As to claim 150, Parris teaches the use of an unfiltered data stream when the signal artifacts do not meet one or more predetermined criteria (claim 1).

19. As to claim 151, Parris teaches data stream monitoring comprises receiving data from one of a non-invasive, minimally invasive, or an invasive glucose sensor (Fig. 1).

20. As to claim 152, Parris teaches an enzymatic glucose sensor ([0003]).

21. As to claim 153, Parris teaches the monitoring of a pH ([0171]).

22. As to claim 154, Parris teaches the use of linear regression ([0124]).

23. As to claim 155, Parris teaches continual correction ([0072]).

24. As to claim 158, Parris teaches the discarding of signal artifacts (error correction inherently throws out the signal artifacts).

25. As to claim 159, Parris teaches the calibration of the data stream ([0010]).

26. As to claim 161, Parris teaches a method for processing data from a glucose sensor, comprising monitoring a data stream from a glucose sensor (Abs), calibrating the data stream ([0117]), detecting transient non-glucose related signals and evaluating a severity of the artifact and replacing at least some of the signal values with one or more estimated glucose values ([0239-0243]). Parris fails to teach that the evaluation of the severity is based in part on rate of change, acceleration, or a physiological feasibility of one or more of the calibrated glucose values. However, Mastrototaro teaches a

teaches a glucose monitor calibration method which determines a severity of a signal artifact and replaces one of the signal artifacts with estimated glucose values, wherein the severity rate of change (col. 9 lines 22-42 - limits are set to depend on acceptable amounts of change from one data point to another) which is equivalent to acceleration. As such, it would have been obvious to one of ordinary skill in the art to modify the method of processing glucose measurement data as taught by Parris with the various methods of determining a severity of a signal artifact as taught by Mastrototaro to obtain results that are more accurately reflective of the user's glucose measurements.

27. As to claim 162, Parris teaches the application of one of a plurality of signal estimation algorithm factors in response to the severity of the signal artifacts (Fig. 13).

28. As to claim 163, Parris teaches the application of a single algorithm with a plurality of parameters that are selectively applied to the algorithm (Fig. 13; several models use a plurality of parameters).

29. As to claim 164, Parris teaches a plurality of distinct algorithms (Fig. 13).

30. As to claim 165, Parris teaches the selective application of a predetermined algorithm that comprises a set of parameters whose values depend on the severity of the signal artifacts ([0248]).

31. As to claim 166, Parris teaches replacing signal artifacts comprises outputting data representative of one or more of the estimated glucose values including a numeric representation ([0243]).

32. As to claim 167, Parris teaches the use of filtered data streams when the signal artifacts meet one or more predetermined criteria. ([0176-0177] - the use of the

predictive kinetic method is capable of being used during error causing physiological phenomena such as temperature).

33. As to claim 168, Parris teaches the use of an unfiltered data stream when the signal artifacts do not meet one or more predetermined criteria (claim 1).

34. As to claim 169, Parris teaches data stream monitoring comprises receiving data from one of a non-invasive, minimally invasive, or an invasive glucose sensor (Fig. 1).

35. As to claim 170, Parris teaches an enzymatic glucose sensor ([0003]).

36. As to claim 171, Parris teaches the monitoring of a pH ([0171]).

37. As to claim 172, Parris teaches the use of linear regression ([0124]).

38. As to claim 173, Parris teaches continual correction ([0072]).

39. As to claim 174, Parris teaches the discarding of signal artifacts (error correction inherently throws out the signal artifacts).

40. As to claim 175, Parris teaches the calibration of the data stream ([0010]).

41. As to claim 177, Parris teaches the application of one of a plurality of signal estimation algorithm factors in response to the severity of the signal artifacts (Fig. 13).

42. As to claim 178, Parris teaches the application of a single algorithm with a plurality of parameters that are selectively applied to the algorithm (Fig. 13; several models use a plurality of parameters).

43. As to claim 179, Parris teaches a plurality of distinct algorithms (Fig. 13).

44. As to claim 180, Parris teaches the selective application of a predetermined algorithm that comprises a set of parameters whose values depend on the severity of the signal artifacts ([0248]).

45. As to claim 181, Parris teaches replacing signal artifacts comprises outputting data representative of one or more of the estimated glucose values including a numeric representation ([0243]).

46. As to claim 182, Parris teaches the use of filtered data streams when the signal artifacts meet one or more predetermined criteria. ([0176-0177] - the use of the predictive kinetic method is capable of being used during error causing physiological phenomena such as temperature).

47. As to claim 183, Parris teaches the use of an unfiltered data stream when the signal artifacts do not meet one or more predetermined criteria (claim 1).

48. As to claim 184, Parris teaches data stream monitoring comprises receiving data from one of a non-invasive, minimally invasive, or an invasive glucose sensor (Fig. 1).

49. As to claim 185, Parris teaches an enzymatic glucose sensor ([0003]).

50. As to claim 186, Parris teaches the monitoring of a pH ([0171]).

51. As to claim 187, Parris teaches the use of linear regression ([0124]).

52. As to claim 188, Parris teaches continual correction ([0072]).

53. As to claim 189, Parris teaches the discarding of signal artifacts (error correction inherently throws out the signal artifacts).

54. As to claim 190, Parris teaches the calibration of the data stream ([0010]).

55. As to claim 192, Parris teaches the application of one of a plurality of signal estimation algorithm factors in response to the severity of the signal artifacts (Fig. 13).

56. As to claim 193, Parris teaches the application of a single algorithm with a plurality of parameters that are selectively applied to the algorithm (Fig. 13; several models use a plurality of parameters).

57. As to claim 194, Parris teaches a plurality of distinct algorithms (Fig. 13).

58. As to claim 195, Parris teaches the selective application of a predetermined algorithm that comprises a set of parameters whose values depend on the severity of the signal artifacts ([0248]).

59. As to claim 196, Parris teaches replacing signal artifacts comprises outputting data representative of one or more of the estimated glucose values including a numeric representation ([0243]).

60. As to claim 197, Parris teaches the use of filtered data streams when the signal artifacts meet one or more predetermined criteria. ([0176-0177] - the use of the predictive kinetic method is capable of being used during error causing physiological phenomena such as temperature).

61. As to claim 198, Parris teaches the use of an unfiltered data stream when the signal artifacts do not meet one or more predetermined criteria (claim 1).

62. As to claim 199, Parris teaches data stream monitoring comprises receiving data from one of a non-invasive, minimally invasive, or an invasive glucose sensor (Fig. 1).

63. As to claim 200, Parris teaches an enzymatic glucose sensor ([0003]).

64. As to claim 201, Parris teaches the monitoring of a pH ([0171]).

65. As to claim 202, Parris teaches the use of linear regression ([0124]).

66. As to claim 203, Parris teaches continual correction ([0072]).

67. As to claims 204 and 205, Mastrototaro teaches the initiation of an artifacts replacement step when the artifacts meet one or more predetermined data and the termination of the step if it does not (col. 8 lines 38-56).

68. As to claim 206, Parris teaches the discarding of signal artifacts (error correction inherently throws out the signal artifacts).

69. As to claim 207, Parris teaches the calibration of the data stream ([0010]).

70. As to claims 209 and 210, Mastrototaro teaches the filtering of data (col. 17 lines 61-63).

71. As to claim 211, Parris teaches the use of raw data stream (prior to processing, data is inherently raw).

72. As to claims 213-215, Mastrototaro teaches the shifting of the sensitivity ratio depending on frequency and amplitude, amongst other signals (col. 11 lines 28-38). Mastrototaro does not disclose expressly the detection of high frequency cycles, low amplitude noise, and measuring amplitudes of high frequency cycles. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect high frequency cycles, low amplitude noise, and measuring amplitudes of high frequency cycles because applicant has not disclosed that the detection of these parameters provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Mastrototaro's teachings to perform equally well with either the detection disclosed by Mastrototaro or those claimed by the applicant. As such, it would have been prima facie obvious to one of ordinary skill in the art to modify the teachings of Parris and

Mastrototaro to obtain the features found in claims 213-215 as a matter of obvious design choice as they fail to patentably distinguish over the stated prior art.

73. As to claims 216-218, Parris teaches a display for outputting data ([0147]).

74. As to claim 219, Mastrototaro teaches evaluating whether the glucose values is outside a predetermined range (col. 10 lines 26-38) that is derived from a projected rate of change or acceleration (col. 9 lines 22-42).

75. As to claims 220-221, Mastrototaro teaches the discarding of estimated values if it is outside the predetermined range (col. 10 lines 26-38) and replaced with a predetermined limit value (col. 8 lines 38-56).

76. As to claim 222, Parris teaches storing values ([0147]).

77. As to claim 223, Parris teaches a display ([0147]).

78. As to claims 224-225, Mastrototaro teaches a maximum-average calculation where the maximum value for an interval is averaged with at least one maximum value associated with a previous interval (col. 8 line 67 to col. 9 line 2 – use of all data points for averaging include using the maximum values).

79. As to claim 226, Mastrototaro teaches that the interval comprises a time period (col. 2 lines 12-20).

80. As to claim 227, Mastrototaro teaches the determination of a ratio and replacing the values if the ratio is outside a predetermined range (col. 12 lines 31-40).

81. As to claim 233, Parris teaches a display for outputting data ([0147]).

82. As to claims 234 and 235, Mastrototaro teaches the filtering of data (col. 17 lines 61-63).

83. As to claim 236, Parris teaches the use of raw data stream (prior to processing, data is inherently raw).

84. As to claim 238, Mastrototaro teaches the shifting of the sensitivity ratio depending on frequency and amplitude, amongst other signals (col. 11 lines 28-38). Mastrototaro does not disclose expressly the detection of high frequency cycles. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect high frequency cycles because applicant has not disclosed that the detection of this parameter provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Mastrototaro's teachings to perform equally well with either the detection disclosed by Mastrototaro or those claimed by the applicant. As such, it would have been prima facie obvious to one of ordinary skill in the art to modify the teachings of Parris and Mastrototaro to obtain the feature found in claim 238 as a matter of obvious design choice as they fail to patentably distinguish over the stated prior art.

85. As to claims 239 and 240, Parris teaches a display for outputting data.

86. As to claim 241, Mastrototaro teaches evaluating whether the glucose values is outside a predetermined range (col. 10 lines 26-38) that is derived from a projected rate of change or acceleration (col. 9 lines 22-42).

87. As to claims 242-243, Mastrototaro teaches the discarding of estimated values if it is outside the predetermined range (col. 10 lines 26-38) and replaced with a predetermined limit value (col. 8 lines 38-56).

88. As to claim 244, Parris teaches storing values ([0147]).

89. As to claim 245, Parris teaches a display ([0147]).

90. As to claims 246-247, Mastrototaro teaches a maximum-average calculation where the maximum value for an interval is averaged with at least one maximum value associated with a previous interval (col. 8 line 67 to col. 9 line 2 – use of all data points for averaging include using the maximum values).

91. As to claim 248, Mastrototaro teaches the determination of a ratio and replacing the values if the ratio is outside a predetermined range (col. 12 lines 31-40).

92. As to claim 254, Parris teaches a display for outputting data ([0147]).

93. As to claims 255-256, Mastrototaro teaches the filtering of data (col. 17 lines 61-63).

94. As to claim 257, Parris teaches the use of raw data stream (prior to processing, data is inherently raw).

95. As to claim 258, Mastrototaro teaches the comparison of the rate of change with a preselected value (Fig. 9).

96. As to claims 259-260, Parris teaches a display for outputting data ([0147]).

97. As to claim 261, Mastrototaro teaches evaluating whether the glucose values is outside a predetermined range (col. 10 lines 26-38) that is derived from a projected rate of change or acceleration (col. 9 lines 22-42).

98. As to claims 262-263, Mastrototaro teaches the discarding of estimated values if it is outside the predetermined range (col. 10 lines 26-38) and replaced with a predetermined limit value (col. 8 lines 38-56).

99. As to claim 264, Parris teaches storing values ([0147]).

100. As to claim 265, Parris teaches a display ([0147]).

101. As to claims 266-267, Mastrototaro teaches a maximum-average calculation where the maximum value for an interval is averaged with at least one maximum value associated with a previous interval (col. 8 line 67 to col. 9 line 2 – use of all data points for averaging include using the maximum values).

102. As to claim 268, Mastrototaro teaches that the interval comprises a time period (col. 2 lines 12-20).

103. As to claim 269, Mastrototaro teaches the determination of a ratio and replacing the values if the ratio is outside a predetermined range (col. 12 lines 31-40).

104. As to claim 270, Parris teaches a display for outputting data ([0147]).

105. As to claims 271 and 272, Mastrototaro teaches the filtering of data (col. 17 lines 61-63).

106. As to claim 273, Parris teaches the use of raw data stream (prior to processing, data is inherently raw).

107. As to claim 274, Mastrototaro teaches that the frequency content comprises frequencies contained within the data stream (inherent, as frequency content is inherently derived from the data stream).

108. As to claim 275, Mastrototaro teaches the shifting of the sensitivity ratio depending on frequency and amplitude, amongst other signals (col. 11 lines 28-38). Mastrototaro does not disclose expressly the detection of data stream that has high frequency. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect data stream that has high

frequency because applicant has not disclosed that the detection of this parameter provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Mastrototaro's teachings to perform equally well with either the detection disclosed by Mastrototaro or those claimed by the applicant. As such, it would have been prima facie obvious to one of ordinary skill in the art to modify the teachings of Parris and Mastrototaro to obtain the feature found in claim 275 as a matter of obvious design choice as they fail to patentably distinguish over the stated prior art.

109. As to claims 276-277, Parris teaches a display for outputting data ([0147]).

110. As to claim 278, Mastrototaro teaches evaluating whether the glucose values is outside a predetermined range (col. 10 lines 26-38) that is derived from a projected rate of change or acceleration (col. 9 lines 22-42).

111. As to claims 279-280, Mastrototaro teaches the discarding of estimated values if it is outside the predetermined range (col. 10 lines 26-38) and replaced with a predetermined limit value (col. 8 lines 38-56).

112. As to claim 281, Parris teaches storing values ([0147]).

113. As to claim 282, Parris teaches a display ([0147]).

114. As to claims 283-284, Mastrototaro teaches a maximum-average calculation where the maximum value for an interval is averaged with at least one maximum value associated with a previous interval (col. 8 line 67 to col. 9 line 2 – use of all data points for averaging include using the maximum values).

115. As to claim 285, Mastrototaro teaches that the interval comprises a time period (col. 2 lines 12-20).

116. As to claim 286, Mastrototaro teaches the determination of a ratio and replacing the values if the ratio is outside a predetermined range (col. 12 lines 31-40).

117. As to claims 293, Mastrototaro teaches the shifting of the sensitivity ratio depending on frequency and amplitude, amongst other signals (col. 11 lines 28-38). Mastrototaro does not disclose expressly the detection of high frequency cycles. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect high frequency cycles because applicant has not disclosed that the detection of this parameter provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Mastrototaro's teachings to perform equally well with either the detection disclosed by Mastrototaro or those claimed by the applicant. As such, it would have been prima facie obvious to one of ordinary skill in the art to modify the teachings of Parris and Mastrototaro to obtain the feature found in claim 293 as a matter of obvious design choice as they fail to patentably distinguish over the stated prior art.

118. As to claim 294, Parris teaches the application of one of a plurality of signal estimation algorithm factors in response to the severity of the signal artifacts (Fig. 13).

119. As to claim 295, Parris teaches the application of a single algorithm with a plurality of parameters that are selectively applied to the algorithm (Fig. 13; several models use a plurality of parameters).

120. As to claim 296, Parris teaches a plurality of distinct algorithms (Fig. 13).

121. As to claim 297, Parris teaches the selective application of a predetermined algorithm that comprises a set of parameters whose values depend on the severity of the signal artifacts ([0248]).

122. As to claim 298, Parris teaches replacing signal artifacts comprises outputting data representative of one or more of the estimated glucose values including a numeric representation ([0243]).

123. As to claim 299, Parris teaches the use of filtered data streams when the signal artifacts meet one or more predetermined criteria. ([0176-0177] - the use of the predictive kinetic method is capable of being used during error causing physiological phenomena such as temperature).

124. As to claim 300, Parris teaches the use of an unfiltered data stream when the signal artifacts do not meet one or more predetermined criteria (claim 1).

125. As to claim 301, Parris teaches data stream monitoring comprises receiving data from one of a non-invasive, minimally invasive, or an invasive glucose sensor (Fig. 1).

126. As to claim 302, Parris teaches an enzymatic glucose sensor ([0003]).

127. As to claim 303, Parris teaches the monitoring of a pH ([0171]).

128. As to claim 304, Parris teaches the use of linear regression ([0124]).

129. As to claim 305, Parris teaches continual correction ([0072]).

130. As to claims 306 and 307, Mastrototaro teaches the initiation of an artifacts replacement step when the artifacts meet one or more predetermined data and the termination of the step if it does not (col. 8 lines 38-56).

131. As to claim 308, Parris teaches the discarding of signal artifacts (error correction inherently throws out the signal artifacts).

132. As to claim 309, Parris teaches the calibration of the data stream ([0010]).

133. As to claim 311, Parris teaches a display for outputting data ([0147]).

134. As to claims 312-313, Mastrototaro teaches the filtering of data (col. 17 lines 61-63).

135. As to claim 314, Parris teaches the use of raw data stream (prior to processing, data is inherently raw).

136. As to claim 316, Mastrototaro teaches the shifting of the sensitivity ratio depending on frequency and amplitude, amongst other signals (col. 11 lines 28-38). Mastrototaro does not disclose expressly the detection of high frequency cycles. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect high frequency cycles because applicant has not disclosed that the detection of this parameter provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Mastrototaro's teachings to perform equally well with either the detection disclosed by Mastrototaro or those claimed by the applicant. As such, it would have been prima facie obvious to one of ordinary skill in the art to modify the teachings of Parris and Mastrototaro to obtain the feature found in claim 316 as a matter of obvious design choice as they fail to patentably distinguish over the stated prior art.

137. As to claims 317-318, Parris teaches a display for outputting data ([0147]).

138. As to claim 319, Mastrototaro teaches evaluating whether the glucose values is outside a predetermined range (col. 10 lines 26-38) that is derived from a projected rate of change or acceleration (col. 9 lines 22-42).

139. As to claims 320-321, Mastrototaro teaches the discarding of estimated values if it is outside the predetermined range (col. 10 lines 26-38) and replaced with a predetermined limit value (col. 8 lines 38-56).

140. As to claim 322, Parris teaches storing values ([0147]).

141. As to claim 323, Parris teaches a display ([0147]).

142. As to claims 324-325, Mastrototaro teaches a maximum-average calculation where the maximum value for an interval is averaged with at least one maximum value associated with a previous interval (col. 8 line 67 to col. 9 line 2 – use of all data points for averaging include using the maximum values).

143. As to claim 326, Mastrototaro teaches the determination of a ratio and replacing the values if the ratio is outside a predetermined range (col. 12 lines 31-40).

144. Claims 160, 176, 191, 208, and 310 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parris et al. (US 2002/0026110) in view of Mastrototaro (USP #6,424,847and further in view of Desai et al. (US 2003/0050546)

145. As to claim 160, the combined teachings of Parris and Mastrototaro do not teach the step of detecting non-glucose related artifacts to be performed on the calibrated data stream. However, Desai teaches an analyte sensor with an initial calibration and re-calibration of the sensor ([0079]; [0282]). As such, it would have been obvious to one

of ordinary skill in the art to modify the method for processing data taught by Parris incorporating the method of determining severity of the signal artifact as taught by Mastrototaro to further process the removal of signal artifacts on a pre-calibrated data stream as taught by Desai.

146. Claims 212, 237, 292, 315 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parris et al. (US 2002/0026110) in view of Mastrototaro (USP #6,424,847) and further in view of Routt et al. (US 2005/0101847).

147. As to claims 212, 237, 292, 315, the combined teachings of Parris and Mastrototaro fail to teach high pass filtering. Routt, in a method for determining blood glucose concentrations, teach the use of a high pass filter ([0062]). As such, it would have been obvious to one of ordinary skill in the art to modify the method for processing data taught by Parris incorporating the method of determining severity of the signal artifact as taught by Mastrototaro to incorporate a high pass filter to eliminate data that will be irrelevant to the measurement results.

148. Claims 228-232, 249-253, 287-291, and 327-331 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parris et al. (US 2002/0026110) in view of Mastrototaro (USP #6,424,847) and further in view of Deutsch ("Time series analysis and control of blood glucose levels in diabetic patients").

149. As to claims 228, 249, 287, and 327, the combined teachings of Parris and Mastrototaro fail to teach the use of a time series analysis based on a variance of signal

over a window of data. Deutsch teaches the use of time series analysis of blood glucose data to decompose data into clinically related components. As such, it would have been obvious to one of ordinary skill in the art to modify the method for processing data taught by Parris incorporating the method of determining severity of the signal artifact as taught by Mastrototaro to further incorporate the use of time series analysis as taught by Deutsch as a means for identifying patterns in time series data for higher accuracy in the interpretation of data.

150. As to claims 229-232, 250-253, 288-291, and 328-331, the combined teachings of Parris, Mastrototaro, and Deutsch fails to expressly teach a window of data at 15, 30, 45, and 60 minutes. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize a window of data at those specified minutes because the applicant has not disclosed that these specific time periods provide a particular advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the combined teachings of Parris, Mastrototaro, and Deutsch to perform equally as well as applicant's as sampling can be done over any desired period of time. Therefore, it would have been prima facie obvious to modify the combined teachings of Parris, Mastrototaro, and Deutsch to obtain the invention as specified in claims 229-232, 250-253, 288-291, and 328-331, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the stated prior arts.

Response to Arguments

151. Applicant's arguments filed October 23rd, 2009 have been fully considered but they are not persuasive.

152. As to claim 160, applicant has referred to paragraphs [0352] and [0353] of the specification as providing support for the limitation of “detecting transient non-glucose related signal artifacts in the data stream is performed on the calibrated data stream”. However, upon review, it does not appear that these paragraphs provide support for such a feature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon-Fri (9-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
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3/26/10